

Center for Devices and Radiological Health

Performance Standard for Electrode Lead Wires and Patient Cables

Office of Compliance

March 16, 1998

Dear Medical Device Manufacturer or Importer:

This letter is to remind you of your obligation to comply with the Performance Standard for Electrode Lead Wires and Patient Cables (Code of Federal Regulations, Chapter 21, Part 898), which becomes effective for certain devices on May 11, 1998. Enclosed for your information are copies of a final guidance document regarding this standard, as well as a copy of the final rule, and excerpts from the referenced international standard, IEC 60601-1. The agency is accepting comments on the guidance document, as it is being implemented. A forthcoming Notice of Availability in the Federal Register will provide instructions for submitting your comments on the guidance document to the agency.

For further information regarding compliance with the Performance Standard for Electrode Lead Wires and Patient Cables, please contact Stewart Crumpler in the Office of Compliance at 301-594-4659, or via FAX at 301-594-4672.

Sincerely yours,
Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

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Guidance Document on the Performance Standard for Electrode Lead Wires and Patient Cables

This document is intended to provide guidance. It represents the Agency's current thinking on implementation of the Performance Standard for Electrode Lead Wires and Patient Cables. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Director, Office of Compliance
Center for Devices and Radiological Health

Document issued on: March 9, 1998

After the close of the initial comment period, comments and suggestions may be submitted at any time for Agency consideration to Stewart Crumpler, Office of Compliance, 2098 Gaither Road, Rockville, Maryland 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Stewart Crumpler at (301) 594-4659, or via FAX at (301) 594-4672.

Additional Copies: World Wide Web/CDRH home page <http://www.fda.gov/cdrh>

or

CDRH Facts on Demand at 1-800-899-0381

or

301-827-0111, specify number 1197 when prompted for the document shelf number.

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health
Rockville, MD 20850**

**Guidance Document on the Performance Standard for
Electrode Lead Wires and Patient Cables**

The Performance Standard for Electrode Lead Wires and Patient Cables, found in Title 21 Code of Federal Regulations (CFR), part 898, was published in the Federal Register on May 9, 1997 [62 FR 25497]. The performance standard becomes effective for certain devices on May 11, 1998.

This guidance document represents the agency's initial thinking on implementation of the performance standard for electrode lead wires and patient cables. This guidance does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both. Due to the public health risks associated with the use of unprotected electrode lead wires and patient cables, the agency is accepting public input while the guidance is being implemented.

The performance standard was promulgated to address the electrocution hazard posed by unprotected patient electrical connectors. Copies of the final rule are also available through the Division of Small Manufacturers Assistance via Facts-on-Demand at 800-899-0381, or 301-827-0111, or from the CDRH Web Page at:

<http://www.fda.gov/cdrh/comp/fr0509af.html>

or

<http://www.fda.gov/cdrh/comp/leadwire.html>

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<http://www.fda.gov/cdrh/comp/fr0509ap.pdf>

This is the first mandatory medical device performance standard, and it is being implemented in two phases. Beginning on May 11, 1998, all electrode lead wires or patient cables intended for use with any of the following devices must comply with the standard:

- Breathing Frequency Monitors
- Ventilatory Effort Monitors (Apnea Detectors)
- Electrocardiographs (ECGs)
- Radio Frequency Physiological Signal Transmitters and Receivers
- Cardiac Monitors
- Electrocardiograph Electrodes (including Pre-wired ECG Electrodes)
- Patient Transducer and Electrode Cables (including Connectors)
- Medical Magnetic Tape Recorders (e.g., Holter Monitors)
- Arrhythmia Detectors and Alarms
- Telephone Electrocardiograph Transmitters and Receivers

Replacement electrode lead wires and patient cables that are intended for use with any of the above listed devices must also comply with the performance standard beginning on May 11, 1998. The ten devices included in this first phase of implementation are those which pose the greatest potential hazard (e.g., those with reported macroshock deaths or injuries, and certain cardiac monitoring devices used outside healthcare facilities).

By reference, the performance standard incorporates the specific requirements of the international standard, IEC 60601-1, subclause 56.3(c), which requires leads to be constructed in such a manner as to preclude patient contact with hazardous voltages (or for certain devices, contact with electrical ground). Specific tests for compliance include conductive contact with a flat conductive surface, conductive contact with the inside of a socket connector, and conductive contact when plugged into an electrical (mains) socket or power cord. While it cannot be posted to the CDRH Web Page, single copies of the referenced IEC subclause, with test criteria and rationale, are available to affected manufacturers on request, from the Office of Compliance at the telephone or FAX numbers listed at the end of this guidance document.

Compliance is determined by the design of the electrode lead wire at the end remote from the patient. Most (if not all) single pole, exposed pin lead wires (regardless of size) and some exposed multi-pin connectors are non-compliant with this standard. The Center is aware of various lead wire designs that do comply, including recessed sockets, recessed or shielded pins, and shielded multi-pin connectors. To meet the standard, a compliant patient cable must be compatible with a compliant lead wire. Questions regarding the compliance status of specific electrode lead wire and patient

Attachment E CDRH Final Guidance Cover Sheet

Page 4 of 5

cable configurations should be directed to the Office of Compliance, at the telephone or FAX numbers listed at the end of this guidance document.

As stated in the preamble to the final rule, design changes and labeling changes made to comply with this performance standard will not require submission of a new premarket notification (510(k)). However, for devices cleared through a premarket approval, information describing the design and labeling changes should be included in the firm's next annual report. Supporting documentation for design changes should also be maintained in the design history file for the device, and will be subject to FDA inspection.

Manufacturers and users have an additional two years to prepare for implementation of the second phase of the standard. Beginning on May 9, 2000, any electrode lead wire or patient cable intended for use with any medical device must comply with the performance standard. During this two year transition period, applicability of the performance standard will be determined by the stated intended use of the electrode lead wire or patient cable, and by circumstances surrounding its promotion, advertising and marketing. To assure compliance with the performance standard after the effective date, manufacturers and their representatives are expected to exercise due diligence in assessing their customers' intended use of replacement electrode lead wires and patient cables marketed for use with existing devices. While not required, manufacturers may also wish to add a statement to their labeling noting compliance with the FDA performance standard (21 CFR, part 898), in order to assist users in selection and management of their electrode lead wires and patient cables. During the transition period, it will also be important to educate customers regarding proper selection of electrode lead wires and patient cables, and to avoid labeling that could be misconstrued regarding intended use. For example, prewired "ECG" electrodes are currently used for many purposes. However, beginning on May 11, 1998, any pre-wired electrodes labeled for "ECG" use must comply with the performance standard.

Continued availability of compatible electrode lead wires and patient cables for existing devices is a concern for the user community. It is anticipated that relatively inexpensive adapters will be available and can be used to economically convert existing devices already in the marketplace to accept compliant electrode lead wires and patient cables. However, the performance standard also accounts for the possibility that there may be circumstances where adapters are not feasible. In such circumstances, the manufacturer may request a variance or exemption from compliance with the standard. Criteria and procedures for submission of a variance/exemption may be found in 21 CFR, section 898.14, and 21 CFR, section 10.30.

For further information regarding compliance with the Performance Standard for



Attachment E CDRH Final Guidance Cover Sheet

Page 5 of 5

Electrode Lead Wires and Patient Cables, please contact Stewart Crumpler in the Office of Compliance at 301-594-4659, or via FAX at 301-594-4672.

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